

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA**

CHARLESTON DIVISION

AMAL EGHNAYEM, et al.,

Plaintiffs,

v.

CIVIL ACTION NO. 2:13-cv-07965

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(Motion for Summary Judgment)

Pending before the court is Defendant Boston Scientific Corporation's ("BSC") Motion for Summary Judgment [Docket 166]. Responses and replies have been filed, and the motion is ripe for review. As set forth below, BSC's Motion for Summary Judgment [Docket 166] is **GRANTED** with respect to the plaintiffs' manufacturing defect and warranty claims and **DENIED** with respect to the plaintiffs' failure to warn claims.

I. Background

This consolidated case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are over 60,000 cases currently pending, over 13,000 of which are in the Boston Scientific Corporation MDL, MDL 2326. In this particular case, the four plaintiffs were surgically implanted with the Pinnacle Pelvic Floor Repair Kit ("the Pinnacle"), a mesh product

manufactured by BSC. (*See* Pretrial Order # 91 [Docket 10], at 1–2).¹ All of the plaintiffs received their surgeries in Florida. The plaintiffs claim that as a result of implantation of the Pinnacle, they have experienced “erosion, mesh contraction, infection, fistula, inflammation, scar tissue, organ perforation, dyspareunia (pain during sexual intercourse), blood loss, neuropathic and other acute and chronic nerve damage and pain, pudendal nerve damage, pelvic floor damage, and chronic pelvic pain.” (*Id.* at 3 (quoting the master complaint)). The plaintiffs allege negligence, design defect, manufacturing defect, failure to warn, breach of express warranty, breach of implied warranty, and punitive damages. (*Id.* at 1-2).

In the instant motion, BSC moves for summary judgment on the plaintiffs’ (1) strict liability and negligent manufacturing claims; (2) breach of express and implied warranty claims; and (3) failure to warn claims [Docket 166].

II. Legal Standards

a. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not “weigh the evidence and determine the truth of the matter.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

¹ I originally consolidated the cases of five plaintiffs implanted with the Pinnacle. (*See* Pretrial Order # 91 [Docket 10] (naming Eghnayem, Dotres, Nunez, Dubois-Jean, and Betancourt as consolidated plaintiffs)). Four plaintiffs now remain in this action. (*See* Order [Docket 35] (removing Dubois-Jean from the consolidated pool)).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some “concrete evidence from which a reasonable juror could return a verdict in his [or her] favor.” *Anderson*, 477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere “scintilla of evidence” in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves-Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm’ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds*, 490 U.S. 228 (1989).

b. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law. Here, the plaintiffs are Florida residents who were implanted with the Pinnacle in Florida, but filed their complaints directly into the MDL in the Southern District of West Virginia. “For cases that originate elsewhere and are directly filed into the MDL, I will follow the better-reasoned authority that applies the choice-of-law rules of the originating jurisdiction, which in our case is the state in which the plaintiff was implanted with the product.” *Sanchez v. Boston Scientific Corp.*, 2:12-cv-05762, 2014 WL 202787, at *4 (S.D. W. Va. Jan. 17, 2014); (*see also* Pretrial Order # 14, MDL 2326, at 2 (“A ‘Directly Filed Case’ is a case filed in

the Southern District of West Virginia for inclusion in this MDL, but the Southern District of West Virginia does not necessarily have personal jurisdiction over the parties.”)). Florida is the originating jurisdiction and the parties agree that the court must consult Florida’s choice-of-law principles to determine the substantive law applicable to the plaintiffs’ claims.

In *Bishop v. Florida Specialty Paint Co.*, the Florida Supreme Court announced a new approach for choice of law questions concerning tort: “Instead of clinging to the traditional *lex loci delicti* rule, we now adopt the ‘significant relationship[] test’ as set forth in the Restatement (Second) of Conflict of Laws §§ 145-146 (1971)[.]” 389 So. 2d 999, 1001 (Fla. 1980). Florida courts have continued to adhere to the significant relationship test set forth in *Bishop*. See e.g., *Rosado v. DaimlerChrysler Fin. Servs. Trust*, 1 So. 3d 1200, 1203 (Fla. Dist. Ct. App. 2009); see also *Connell v. Riggins*, 944 So. 2d 1174, 1176 (Fla. Dist. Ct. App. 2006). In adopting this test, the *Bishop* court reiterated the language set forth in § 146 of the Restatement, noting that “[t]he state where the injury occurred would, under most circumstances, be the decisive consideration in determining the applicable choice of law.” 389 So. 2d at 1001. The plaintiffs here are Florida residents, underwent Pinnacle device implantation surgery in Florida, and allegedly suffered injury in Florida. (See Pretrial Order # 91 [Docket 10], at 1). Therefore, I **FIND** that the substantive laws of Florida apply to the issues in this case.²

III. Analysis

a. Manufacturing Defect Claims

First, BSC argues that the plaintiffs’ strict liability and negligent manufacturing claims fail for lack of evidence. (BSC’s Mem. of Law in Supp. of Its Mot. for Summ. J. (“Def.’s Mem.

²I previously determined that in regard to the plaintiffs’ punitive damages claims, Florida has a more significant relationship to the issue of punitive damages than Massachusetts. (See Mem. Op. & Order [Docket 232], at 4-9).

Supp.”) [Docket 168], at 2). In its reply, BSC also contends that it is entitled to judgment as a matter of law on the manufacturing defect claims because the plaintiffs did not respond to BSC’s motion on this issue. (BSC’s Reply in Supp. of Its Mot. for Summ. J. (“Def.’s Reply”) [Docket 183], at 1). However, the Fourth Circuit rejected this argument in *Custer v. Pan American Life Ins. Co.*:

In this case, the plaintiff failed to respond to the defendants’ motion for summary judgment, despite repeated notices to do so. This failure to respond, however, does not fulfill the burdens imposed on moving parties by Rule 56. Section (c) of Rule 56 requires that the moving party establish, in addition to the absence of a dispute over any material fact, that it is “entitled to a judgment as a matter of law.” Fed. R. Civ. P. 56(c). Although the failure of a party to respond to a summary judgment motion may leave uncontroverted those facts established by the motion, the moving party must still show that the uncontroverted facts entitle the party to “a judgment as a matter of law.” The failure to respond to the motion does not automatically accomplish this. Thus, the court, in considering a motion for summary judgment, must review the motion, even if unopposed, and determine from what it has before it whether the moving party is entitled to summary judgment as a matter of law. This duty of the court is restated in section (e) of the rule, providing, “if the adverse party does not so respond, summary judgment, *if appropriate*, shall be entered against the adverse party.” Fed. R. Civ. P. 56(e) (emphasis added).

27 F.3d 410, 416 (4th Cir. 1993). Therefore, I proceed to consider the merits of BSC’s motion regarding the plaintiffs’ manufacturing defect claims.

In *West v. Caterpillar Tractor, Co.*, the Supreme Court of Florida adopted Section 402A of the Restatement (Second) of Torts as the standard for strict liability. 336 So. 2d 80, 87 (Fla. 1976). Accordingly, in Florida,

[i]n order to hold a manufacturer liable on the theory of strict liability in tort, the user must establish the manufacturer’s relationship to the product in question, the defect and unreasonably dangerous condition of the product, and the existence of the proximate causal connection between such condition and the user’s injuries or damages.

Id. at 86-87. A manufacturing defect results from manufacturing flaws caused by a “miscarriage in the manufacturing process which produces an unintended result.” *Cassisi v. Maytag Co.*, 396 So. 2d 1140, 1145 (Fla. Dist. Ct. App. 1981).

The plaintiffs did not respond to BSC’s motion for summary judgment on this issue, but even if I consider the allegations in the Master Long Form Complaint, no material fact exists suggesting that the Pinnacle had manufacturing defects. (*See generally* Master Long Form Compl. & Jury Demand, MDL 2326). For example, the plaintiffs allege that “the material from which the Products are made is biologically incompatible with human tissue” and that the products were “unreasonably susceptible” to shrinkage, contraction, elongation, and deformation. (*Id.* at ¶¶ 27, 30, 31; *see also id.* at ¶ 36 (including a list of product defects)). These arguments, however, relate to the Pinnacle’s design and behavior after implantation. The plaintiffs point to no evidence that there was a “miscarriage” in the Pinnacle’s manufacturing process “which produce[d] an unintended result.” *Cassisi*, 396 So. 2d at 1145.

With regard to negligent manufacturing, although Florida has rejected the notion that strict products liability and negligence are “functionally equivalent,” the plaintiffs still fail to offer any evidence of a flaw in the manufacturing process sufficient to show BSC did not act with reasonable care. *See* Spencer H. Silverglate, *The Restatement (Third) of Torts Products Liability: The Tension Between Product Design & Product Warnings*, 75-DEC Fla. B.J. 10 (2001) (citing *High v. Westinghouse Elec. Corp.*, 610 So. 2d 1259 (Fla. 1992)). Accordingly, BSC’s motion for summary judgment on the manufacturing defect claims is **GRANTED**, and these claims are **DISMISSED**.

b. Warranty Claims

Next, BSC argues that the plaintiffs' breach of express and implied warranty claims fail for lack of privity. (Def.'s Mem. Supp. [Docket 168], at 2). Again, in its reply, BSC contends that it is entitled to judgment as a matter of law on the warranty claims because the plaintiffs did not respond to BSC's motion on the issue. (Def.'s Reply [Docket 183], at 1). I previously rejected this argument, as discussed above. Therefore, I proceed to consider the merits of BSC's motion regarding the plaintiffs' warranty claims.

Florida recognizes three categories of warranties: (1) express warranty; (2) implied warranty of merchantability; and (3) implied warranty of fitness for a particular purpose. These warranties are defined in Sections 672.313, 672.314, and 672.315, Florida Statutes (2012). First,

(1) Express warranties by the seller are created as follows:

- (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
- (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.
- (c) Any sample or model which is made part of the basis of the bargain creates an express warranty that the whole of the goods shall conform to the sample or model.

F.S.A. § 672.13. Next, Florida Statutes provide that "a warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind." *Id.* § 672.14. Lastly,

Where the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose.

Id. § 672.315.

Under Florida law, “to recover for the breach of a warranty, either express or implied, the plaintiff must be in privity of contract with the defendant.” *T.W.M. v. Am. Med. Sys., Inc.*, 886 F. Supp. 842, 844 (N.D. Fla. 1995) (citing *Kramer v. Piper Aircraft Corp.*, 520 So. 2d 37 (Fla. 1988)). In *T.W.M.*, the court explains that a warranty “is fundamentally a contract,” which requires privity, and that “[a] plaintiff who purchases a product, but does not buy it directly from the defendant, is not in privity with that defendant.” (*Id.* (dealing with the purchase of a penile implant) (citing 1 White & Summers, *Uniform Commercial Code* § 11-2, at 528 (3d ed. 1988))). Much like the situation in *T.W.M.*, the present complaint does not allege that the plaintiffs purchased the Pinnacle directly from BSC or that they contracted with BSC. Had the plaintiffs responded to BSC’s motion on this issue with additional facts, my decision may have been different.³ Accordingly, BSC’s motion for summary judgment on the plaintiffs’ warranty claims is **GRANTED**, and these claims are **DISMISSED**.

c. Failure to Warn Claims

Lastly, BSC argues that the plaintiffs’ failure to warn claims are barred by Florida’s learned intermediary doctrine. In support of this argument, BSC contends that (1) it did not owe a duty to warn the plaintiffs directly; (2) it provided adequate warnings of the risks associated with the Pinnacle device; and (3) all four plaintiffs’ treating physicians were aware of the risks presented in the Pinnacle directions for use (“DFU”). (*See* Def.’s Mem. Supp. [Docket 168], at 7-15). While I agree that under the learned intermediary doctrine BSC did not have a duty to warn the plaintiffs directly, BSC’s remaining two arguments employ circular and unconvincing logic.

³ For example, in *Ocana v. Ford Motor Co.*, the court discusses the possibility of establishing privity through an agency relationship. *See* 992 So. 2d 319, 325-27 (Fla. Dist. Ct. App. 2008). However, the plaintiffs here do not allege any facts from which I can attempt to ascertain such a relationship.

Florida, like most jurisdictions, follows the learned intermediary doctrine. *See E.R. Squibb & Sons v. Farnes*, 697 So. 2d 825, 827 (Fla. 1997) (stating that Florida law requires the manufacturer of prescription drugs provide an adequate warning only to the physician, or “learned intermediary”). Under that doctrine, the drug or medical device manufacturer’s duty to warn is directed to the physician rather than the patient. *Upjohn Co. v. MacMurdo*, 562 So. 2d 680, 683 (Fla. 1990) (citing *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102, 104 (Fla. 1989)).⁴ Although typically a question of fact, the adequacy of warnings “can become a question of law where the warning is accurate, clear, and unambiguous.” *Felix*, 540 So. 2d at 105. Furthermore, the “causal link between a patient’s injury and the alleged failure to warn is broken when the prescribing physician had ‘substantially the same’ knowledge as an adequate warning from the manufacturer should have communicated to him.” *Beale*, 492 F. Supp. at 1365 (quoting *Christopher v. Cutter Labs.*, 53 F.3d 1184, 1192 (11th Cir. 1995)). Consequently, the questions become whether BSC’s warnings were adequate and whether the plaintiffs’ physicians were truly “learned intermediaries.” *See id.* at 1368-71.

i. Adequacy of Warnings

BSC argues that the Pinnacle DFU was adequate because it “advises physicians of the very injuries for which Plaintiffs seek recovery.” (Def.’s Mem. Supp. [Docket 168], at 9). In its reply, BSC notes that it would be “unreasonable” to hold BSC liable for not characterizing the injuries warned of in a certain way. (Def.’s Reply [Docket 183], at 7 (citing *Upjohn*, 562 So. 3d at 683)). Although BSC’s reasonableness argument has some merit, it is not sufficient to sustain a motion for summary judgment. The plaintiffs have presented evidence that “at least some of

⁴ I note that in *Beale v. Biomet, Inc.*, the Southern District of Florida held that the learned intermediary doctrine applies to prescription medical devices as well as prescription drugs. 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007).

the complications suffered by these Plaintiffs were not identified in the Pinnacle DFU at all.” (Pls.’ Resp. in Opp. to BSC’s Mot. for Summ. J. (“Pls.’ Resp.”) [Docket 178], at 4). The plaintiffs also point out the presence of potentially “qualifying language,” which, in the plaintiffs’ view, minimizes the presented risks and renders the entire DFU inadequate. (*See id.* at 7-8). Accordingly, I **FIND** that the plaintiffs have presented sufficient evidence on the adequacy of BSC’s warnings to show that there is a genuine dispute of material fact.

ii. Proximate Cause

BSC also asserts that the plaintiffs cannot establish proximate cause because all three treating physicians had knowledge of the risks warned of in the Pinnacle DFU. However, I agree with the plaintiffs’ response that BSC’s “circular logic is self-defeating” because there is no evidence that the treating physicians knew of any risks other than those warned of in the DFU. (Pls.’ Resp. [Docket 178], at 13). In its Memorandum in Support, BSC quotes testimony from each treating physician indicating that he read and relied on the DFU. (*See* Def.’s Mem. Supp. [Docket 168], at 12-15). Ms. Betancourt’s physician, Dr. Emilio Gomez-Madrazo, even testified that he had no criticisms of the DFU at the time of Ms. Betancourt’s implantation. (*See id.* at 13). Nevertheless, this testimony fails to support BSC’s argument for two reasons. First, I have already determined that there is a genuine issue of material fact as to the adequacy of the DFU. Therefore, the fact that the physicians had knowledge of the risks in the DFU does not necessarily mean they had knowledge of *all* pertinent risks. Second, the plaintiffs’ response includes unequivocal statements from all three physicians indicating that had they known then what they know now, they would not have chosen to use the Pinnacle for these plaintiffs. Accordingly, I **FIND** that the plaintiffs have presented sufficient evidence of proximate cause to

show that there is a genuine issue of material fact. Therefore, BSC's motion for summary judgment on the failure to warn claims is **DENIED**.

IV. Conclusion

For the reasons discussed above, BSC's motion for summary judgment is **GRANTED** with respect to the plaintiffs' manufacturing defect and warranty claims and **DENIED** with respect to the plaintiffs' failure to warn claims.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: October 27, 2014



JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE